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IN THE

Supreme Court of the United States

OCTOBER TERM, 1991

AMERICAN SOCIETY OF PLASTIC AND RECONSTRUCTIVE SURGEONS, INC. and ROBERT M. GOLDWYN, M.D.,

Petitioners,

v.

CELIA ANDERSON,

Respondent.

On Petition For A Writ Of Certiorari To The Supreme Court Of The State Of Utah

MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE AND BRIEF OF THE AMERICAN MEDICAL ASSOCIATION, AMERICAN DENTAL ASSOCIATION, AMERICAN ACADEMY OF ALLERGY AND IMMUNOLOGY, AMERICAN ACADEMY OF DERMATOLOGY, AMERICAN ACADEMY OF OPHTHALMOLOGY, AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS, AMERICAN ACADEMY OF OTOLARYNGOLOGY-HEAD AND NECK SURGERY, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN COLLEGE OF PHYSICIANS, AMERICAN COLLEGE OF RADIOLOGY, AMERICAN SOCIETY OF ANESTHESIOLOGISTS, AMERICAN UROLOGICAL ASSOCIATION, AND SOCIETY OF NUCLEAR MEDICINE AS AMICI CURIAE IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI

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Pursuant to Rule 37.2 of the Rules of this Court, the American Medical Association, American Dental Association, American Academy of Allergy and Immunology, American Academy of Dermatology, American Academy of Ophthalmology, American Academy of Orthopaedic Surgeons, American Academy of Otolaryngology-Head and Neck Surgery, American College of Obstetricians and Gynecologists, American College of Physicians, American College of Radiology, American Society of Anesthesiologists, American Urological Association, and Society of Nuclear Medicine respectfully move for an order permitting

them to file a brief *amicus curiae*. In support of their motion, *amici* state as follows:

1. *Amici* are nonprofit professional associations collectively representing several hundred thousand physicians and dentists throughout the United States. *Amici* and their members are dedicated to maintaining high quality health care through numerous means, including the promotion and implementation of effective clinical research. They are also committed to ensuring that medical and dental services, particularly specialized services, are available to all persons in need of such treatment, regardless of the individual patient's location. The organizations represented herein are as follows:

a. The American Medical Association ("AMA") is a private, nonprofit organization that was established in 1847 to promote the art and science of medicine. AMA, with over 280,000 members, is the largest physician association in the world.

b. The American Dental Association ("ADA") is a private, nonprofit organization founded in 1859. Its purpose is to encourage the improvement of the oral health of the public and to promote the art and science of dentistry. ADA has 140,000 dentist members, representing approximately 75 percent of the nation's dentists. ADA encourages clinical trials of dental therapeutics and dental materials, instruments, and equipment. It often helps design protocols for such studies. ADA also relies on the results of clinical trials in its various programs for evaluating the safety and efficacy of dental therapeutics and dental materials, instruments, and equipment.

c. The American Academy of Allergy and Immunology ("AAAI") is a private, nonprofit medical specialty society with over 4,200 members. AAAI is the leading medical

organization for allergists and immunologists in the United States.

d. The American Academy of Dermatology ("AAD") is a private, nonprofit medical specialty society with over 8,800 members. AAD is the largest medical organization of dermatologists in the world.

e. The American Academy of Ophthalmology ("AAO") is a private, nonprofit medical specialty society, composed of 16,000, or more than 95 percent, of the nation's ophthalmologists. AAO is the largest group of ophthalmologists in the United States.

f. The American Academy of Orthopaedic Surgeons ("AAOS") is a private, nonprofit medical specialty society with 15,600 members, representing over 90 percent of all eligible, Board-certified orthopaedic surgeons in the United States and Canada. AAOS is the leading medical organization for musculoskeletal specialists. Its Center for Research provides opportunities for Academy-coordinated or Academy-initiated clinical research on a national level.

g. The American Academy of Otolaryngology-Head and Neck Surgery ("AAO-HNS") is a private, nonprofit medical specialty organization with over 9,300 members. AAO-HNS is the leading medical society for physicians specializing in head and neck surgery. Its Office of Research Development helps to coordinate multicenter clinical studies in the otolaryngology field.

h. The American College of Obstetricians and Gynecologists ("ACOG") is a private, nonprofit medical specialty organization with over 30,000 members representing 90 percent of the obstetricians and gynecologists in the United States. ACOG is the leading group of physicians specializing in health care for women. ACOG is currently the reci-

pient of a federal grant to support clinical trials in gynecologic oncology. In addition, many of ACOG's members are involved in clinical trials, and the College is often asked to recommend physicians to serve as advisors to clinical studies.

i. The American College of Physicians ("ACP"), founded in 1919, is a private, nonprofit medical specialty society with over 70,000 members specializing in the field of internal medicine. ACP comprises approximately 70 percent of all physicians in the United States practicing the specialty of internal medicine. It is the largest organization of medical specialists.

j. The American College of Radiology ("ACR") is a private, nonprofit medical specialty society with over 27,000 members. ACR is the largest organization of radiologists in the nation. ACR and its members have had extensive involvement with controlled clinical investigations. In particular, ACR has several contracts with the National Cancer Institute to organize and monitor numerous clinical cancer trials.

k. The American Society of Anesthesiologists ("ASA") is a private, nonprofit medical specialty society with nearly 29,000 members. ASA is the largest group of physicians specializing in the field of anesthesiology.

l. The American Urological Association ("AUA") is a private, nonprofit medical specialty organization with over 8,300 members worldwide. AUA is the leading medical society for physicians specializing in urology and urological surgery. It is currently involved in clinical trials in Benign Prostatic Hypertrophy, and is frequently asked to recommend physicians to serve as advisors to clinical studies.

m. The Society of Nuclear Medicine ("SNM") is a private, nonprofit, medical specialty organization representing approximately 11,000 nuclear medicine physicians, scientists, radiopharmacists, and technologists engaged in clinical practice and research. SNM is the largest organization of nuclear medicine health professionals in the United States.

2. Petitioners raise a question of national significance. If permitted to stand, the Utah Supreme Court's decision to exercise jurisdiction over the American Society of Plastic and Reconstructive Surgeons and Dr. Goldwyn, based solely on their involvement in a national clinical trial, will have a chilling effect on the willingness of medical and dental organizations and their members to participate in multistate clinical investigations. This chilling effect will be pronounced because health care organizations and individual physicians and dentists participate in clinical trials to improve medical science and the public health, rather than for commercial benefit. The Utah Supreme Court's decision also will discourage physicians, dentists, and other health care providers from treating patients from foreign states. Accordingly, the decision could have serious adverse consequences for the advancement of medical science, the quality of health care, and the availability of interstate medical and dental services.

3. The brief that *amici* request permission to file agrees with petitioners that the decision below violates the Due Process Clause of the Fourteenth Amendment. However, *amici*'s brief focuses on the national implications of the Utah Supreme Court's decision, rather than on the specific facts of this case. The brief *amicus curiae* urges that the petition should be granted because (i) the

Utah Supreme Court's exercise of jurisdiction over petitioners is unreasonable in that it fails to consider the important effect that its decision will have on the "shared interest of the several States in furthering fundamental substantive social policies," as required by this Court's decisions in *Asahi Metal Industry Co. v. Super. Court of Calif.*, 480 U.S. 102, 113 (1987), and *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 292 (1980), and (ii) the Utah Supreme Court's ruling conflicts with the majority of lower federal and state court decisions regarding the exercise of personal jurisdiction under the Due Process Clause in malpractice actions against nonresident physicians, dentists, and other health care providers.

4. *Amici* sought the consent of the parties to file the accompanying brief *amicus curiae*. Petitioners consented, but respondent declined to do so. Petitioners' letter of consent is being filed contemporaneously with the Clerk of the Court. *Amici* seek leave to file their brief, in accordance with Rule 37.2. As national medical and dental associations representing thousands of physician and dentist members, *amici's* views on the questions presented will provide the Court with a broad perspective on the adverse practical ramifications for health care policy that will likely result unless the decision below is reversed, and on the need for a uniform interpretation of the Due Process Clause as it applies to the exercise of personal jurisdiction over nonresident health care providers and organizations in malpractice cases.

For the foregoing reasons, *amici* respectfully request that this Court grant their motion for leave to file the accompanying brief *amicus curiae.*

Respectfully submitted,

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INTEREST OF THE AMICI CURIAE

Amici curiae are major national medical and dental associations and specialty societies representing hundreds of thousands of physicians and dentists. Each *amicus* and its members are committed to maintaining progress in medical science and quality health care through numerous means, including the promotion and implementation of effective clinical research. *Amici* are also dedicated to encouraging widespread availability of medical and dental services.

Amici's interest in this case is to provide the Court with certain information regarding the conduct of clinical trials and to share with the Court their understanding of the practical implications for national health care policy of the Utah Supreme Court's ruling. The Utah Supreme Court's decision to exercise jurisdiction over petitioners American Society of Plastic and Reconstructive Surgeons ("ASPRS") and Dr. Goldwyn, based solely on their involvement in a national, multistate clinical trial, is unreasonable because it will discourage medical specialty societies, physicians, dentists, and other health care providers from participating in critically important clinical investigations, thereby retarding the progress of medical and dental research.

The Utah decision will also limit patients' access to interstate health care services, particularly specialized procedures, by discouraging health care providers from treating out-of-state patients. By failing to consider or give meaningful weight to this effect, the decision below conflicts with the decisions of the majority of lower federal and state courts that have been asked to exercise personal jurisdiction over a nonresident physician, dentist, or other health care provider in a malpractice action.

Amici therefore seek to demonstrate that the public interest requires that the petition be granted so that this

Court may address the issues of national importance raised by the Utah decision and reconcile a significant conflict among the lower courts in their interpretation of the limits of the Due Process Clause.

STATEMENT

Amici adopt and incorporate herein petitioners' statement of the case. The following will provide the Court with certain essential background on the conduct of clinical trials.

1. A controlled clinical trial is a planned investigation in medicine in which one group of patients receives a test treatment and another group receives a control treatment; the two groups of patients are later compared on the basis of some pre-defined measure. Meinert, *Clinical Trials: Design, Conduct, and Analysis* 3 (1986) ("Meinert"); Kahan, Neu, Hammons, and Hillman, *The Decision to Institute Clinical Trials of Current Medical Practices* 1 (Rand 1985) ("Kahan"). Patients are usually assigned to one group or the other on a random basis. *Id.*

Controlled clinical trials have become the definitive mechanism for evaluating the therapeutic effectiveness of new drugs and medical devices. American Medical Association Council on Scientific Affairs, *Special Report, Viability of Cancer Clinical Research: Patient Accrual, Coverage, and Reimbursement*, 83 J. Nat'l Cancer Inst. 254 (1991) ("*AMA Special Report*"). They have also been widely used to evaluate the efficacy and cost-effectiveness of new and existing medical procedures. Kahan, *supra*, at 5-6.

Clinical trials are often multicentered with locations in several states and thousands of patient participants. For instance, the National Cancer Institute's Community Clinical Oncology Program covers 34 states and 62 United States communities and involves thousands of patients. Hunter,

et al., Selection Factors in Clinical Trials: Results From the Community Clinical Oncology Program Physician's Patient Log, 71 Cancer Treatment Reports 559 (1987) ("Hunter"). *See also* Office of Technology Assessment, *The Impact of Randomized Clinical Trials on Health Policy and Medical Practice* 8 (1983) ("*OTA Report*") ("Multiple Risk Factor Intervention Trial [involved] 12,866 men at 22 clinical centers to test the effect of a multifactor intervention program on mortality from coronary heart disease").

There are important reasons for conducting clinical trials in many different areas. First, multicenter studies are necessary to generate adequate patient volume. *OTA Report, supra*, at 55. Second, multistate trials allow for the enrollment of a more heterogenous group of patients, which leads to more statistically accurate results. *Id.* Third, the coordinated approach of national clinical trials avoids duplication of effort. *Id.* at 66.

Controlled clinical trials have contributed to countless major medical breakthroughs. For instance, in the cancer area, advances have been achieved in curative therapy for childhood leukemia, Hodgkin's disease, cancer of the testis, and solid tumors in children. Clinical trials have also led to a decreased mortality for premenopausal women with breast cancer. Antman, Schnipper, and Frei, *The Crisis in Clinical Cancer Research, Third-Party Insurance and Investigational Therapy*, 319 N. Eng. J. Med. 46 (1988) ("Antman"). In addition, clinical trials have been used to develop treatments for tuberculosis, AIDS, cardiovascular disease (including the artificial heart), sexually transmitted diseases, and diabetes-related blindness, to name a few.

2. The federal government plays a significant role in the funding, sponsoring, and monitoring of clinical studies. The National Institutes of Health ("NIH") is the prin-

cipal governmental sponsor of controlled clinical trials. Kahan, *supra*, at 13; Meinert, *supra*, at 40-42. According to the NIH Division of Financial Management, the agency allocated nearly $610 million to funding clinical trials in 1990. More than $525 million of this amount, or about 85 percent, was used to sponsor extramural research by private parties. Several other federal agencies also support clinical trials, including the Veterans Affairs Administration, the Department of Defense, and NASA. *OTA Report*, *supra*, at 24-26; Vaitukaitis, *The Future of Clinical Research*, 39 Clinical Research 145 (1991) ("Vaitukaitis").

The Food and Drug Administration requires clinical trials to establish the safety and efficacy of new drug therapies, 21 U.S.C. § 355 (West Supp. 1991); 21 C.F.R. § 312.21 (1990), and certain new medical devices, 21 U.S.C. §§ 360c-k (West Supp. 1991); 21 C.F.R. § 814.20 (1990). The FDA will approve a new drug application only if the safety and efficacy of the new drug are supported by "evidence consisting of adequate and well-controlled investigations, including clinical investigations" that are conducted by qualified experts. 21 U.S.C. § 355(d).

The FDA closely monitors clinical investigations of new drugs. A sponsor of a clinical investigation may not begin the study until it has submitted an investigational new drug application ("IND") and a protocol describing in detail how each phase of the study will be conducted. 21 C.F.R. §§ 312.20, 312.23(a)(6). The FDA regularly audits ongoing clinical investigations. Lisook, *FDA Audits of Clinical Studies: Policy and Procedure*, 30 J. Clin. Pharmacol. 296 (1990).

3. Clinical investigations of new drugs are typically sponsored by pharmaceutical companies. *OTA Report*, *supra* at 19. Private, nonprofit health and medical groups, such as the American Cancer Society, the American Heart

Association, the Juvenile Diabetes Foundation, and the Cystic Fibrosis Foundation also fund clinical trials of new treatments. *Id.*; Vaitukaitis, *supra*, at 145. Academic institutions occasionally sponsor controlled clinical trials, but more often they provide the facilities and personnel for government funded research and assist in recruiting patients to participate in clinical studies. In 1990, the federal government provided nearly $1 billion per year in support of such facilities and activities. *Id.*

As in this case, medical specialty societies regularly assist in the development of government and industry sponsored clinical trials. For instance, *amici* American College of Radiology, American College of Obstetricians and Gynecologists, American Academy of Orthopaedic Surgeons, American Urological Association, and American Academy of Otolaryngology-Head and Neck Surgery each participates or assists in the coordination of large-scale multicenter clinical trials in its respective field. In addition, *amicus* American Dental Association often helps design protocols for clinical trials and relies on the results of such studies in its various programs to evaluate the safety and efficacy of dental therapeutics and dental materials, instruments, and equipment.

Medical and dental societies are regularly asked to identify physicians willing to serve as monitors and investigators for clinical trials. These physicians and dentists are often the primary source of patient participants for clinical studies. *OTA Report*, *supra*, at 11. The medical monitor plays an important role in evaluating the quality of data submitted by the clinical investigators. Cox, Hynds, and Guarino, *The Management of Clinical Studies*, in *New Drug Approval Process* 191 (Guarino, ed. 1987). However, the clinical research monitor generally is not involved in the treatment of individual patients.

SUMMARY OF ARGUMENT

The Utah Supreme Court's exercise of jurisdiction over petitioners violates the reasonableness requirement of the Due Process Clause of the Fourteenth Amendment. *Asahi Metal Industry Co. v. Super. Court of Calif.*, 480 U.S. 102, 113 (1987); *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 292 (1980). The decision to exercise jurisdiction is unreasonable because it is inimical to the "shared interest of the several States in furthering fundamental substantive social policies," *id.*, in that it will discourage medical specialty societies, dental associations, physicians, dentists, and other health care providers from participating in controlled clinical trials. Medical and dental societies and their members participate in clinical studies to further the public health and to advance medical science. They do not participate for commercial benefit. Their incentive to participate in clinical trials will be greatly reduced if they are effectively subject to jurisdiction in every state in which some phase or aspect of a national clinical investigation is conducted. As a result, the progress of important medical research will be impeded.

This case is of national significance because of the key role that clinical trials play in the advancement of medical science and quality health care. In addition, the federal government, as one of the primary sponsors of clinical trials, has a significant national investment in this scientific process. The Utah Supreme Court's failure to consider these national interests directly conflicts with the due process analysis required by this Court's decisions in *Asahi* and *World-Wide Volkswagen*.

The Utah Supreme Court also failed to consider the more generalized effect that its decision will have on the willingness of health care providers to treat out-of-state patients. By exposing a nonresident physician to long-arm

jurisdiction when he has not treated the patient, in Utah or anywhere else, and has no other significant contacts with Utah, the decision will likely limit the availability of out-of-state health care services, particularly highly specialized services. The Utah Supreme Court's failure to consider and give meaningful weight to these interstate implications conflicts with the decisions of the majority of lower federal and state courts that have been asked to exercise jurisdiction over nonresident physicians, dentists, and other health care providers in malpractice actions.

ARGUMENT

I. THE UTAH SUPREME COURT'S EXERCISE OF JURISDICTION OVER PETITIONERS IS UNREASONABLE BECAUSE THE COURT FAILED TO CONSIDER THE ADVERSE EFFECTS THAT THE DECISION WILL HAVE ON THE PROGRESS OF MEDICAL RESEARCH AND QUALITY OF HEALTH CARE.

The Utah Supreme Court's decision is unreasonable because the court utterly failed to consider the chilling effect that its ruling will have on the willingness of medical and dental societies, individual physicians and dentists, and other health care providers to participate in controlled clinical trials. This result is of national significance because it will impede the progress of medical research and the advancement of quality health care.

This Court has established a two-part test for asserting specific jurisdiction over the person under the Due Process Clause of the Fourteenth Amendment. First, due process is satisfied only where the defendant has "purposefully established 'minimum contacts' in the forum state" that give rise to the cause of action. *Burger King v. Rudzewicz*, 471 U.S. 462, 474 (1985) (quoting *International Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)). Second, if

it has been decided that a defendant purposefully established the requisite minimum contacts, a court must determine whether the exercise of personal jurisdiction would offend " 'traditional notions of fair play and substantial justice.' " *Asahi Metal Industry Co. v. Super. Court of Calif.*, 480 U.S. 102, 113 (1987) (quoting *International Shoe*, 326 U.S. at 316). In other words, the court must decide whether it would be reasonable to exercise jurisdiction over the defendant. *Id.* at 113-15 (unreasonable to exercise jurisdiction over Japanese manufacturer of tire valve stems in part because of foreign policy implications). This is not an optional inquiry; the court must address both parts of the due process test before it may exercise long-arm jurisdiction. *Id.*

The determination of reasonableness turns on the analysis of several factors, including "the interests of the forum State" and " 'the shared interest of the several States in furthering fundamental substantive social policies.' " *Asahi*, 480 U.S. at 113 (quoting *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 292 (1980)). Here again, the court *must* weigh all of the reasonableness factors in its decision. *Id.* at 115 ("*World-Wide Volkswagen* also admonished courts to take into consideration the interests of the 'several States'. . . in the advancement of substantive policies"). Even if the forum state has a strong interest in exercising jurisdiction over a nonresident defendant, "the Due Process Clause, acting as an instrument of interstate federalism, may sometimes act to divest the State of its power to render a valid judgment." *World-Wide Volkswagen*, 444 U.S. at 294.

Amici agree with and adopt petitioners' position that their activities in Utah are too attenuated to satisfy the minimum contacts part of the due process test. *Amici*'s purpose here is to show that the exercise of jurisdiction over petitioners is unreasonable because the Utah court

failed to consider the adverse effect that its ruling will have on our national interest in the advancement of medical progress and public health through clinical research.

That there is a strong national interest in the conduct of controlled clinical trials can hardly be disputed. " '[N]o other method for studying the merits of clinical treatment regimens can approach the precision of estimating the effects and the strength of inference permitted by sound [randomized controlled trials].' " Kahan, *supra*, at 6 (citations omitted).[1]

The fact that the federal government is a principal sponsor of clinical trials is further evidence of a strong national interest and investment in this process. Moreover, our nation's system of new drug approval is dependent upon the performance of clinical trials. Clinical trials are also an essential tool in evaluating the cost-effectiveness of alternative therapies.

The Utah Supreme Court's decision comes at a time when clinical research in many fields is already in a state of near crisis. For instance, clinical cancer trials are hindered by the increasing cost of providing care, federal funding constraints, and the reluctance of third party payors to reimburse for investigational treatments. Antman, *supra*, at 46; Durant, *Current Status of Clinical Trials*, 65 Cancer 2371, 2372-73 (1990). The AMA's Council on Scientific Affairs has observed that "This environment has the potential to seriously compromise clinical research

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[1] In the cancer field, for example,

> The ability to administer experimental therapy is fundamental to medical progress. If new treatments cannot be tested, the state of the art will freeze at its current level. To the extent that these newly discovered treatments remain inaccessible to the average cancer patient, lives will be lost unnecessarily.

Wittes, *From Research to Approved Treatment: Overcoming the Obstacles*, 25 Seminars in Hematology 38, 42 (1988).

just at the time when great strides in such fields as molecular biology, genetics, and medical physics argue persuasively for a significant augmentation of the research effort." *AMA Special Report, supra,* at 254.

In addition to these obstacles, the viability of clinical trials is threatened by insufficient patient accrual or recruitment. Many clinical studies are being delayed or aborted because of an inability to obtain subject populations of sufficient size or heterogeneity.[2] Wittes and Friedman, *Accrual to Clinical Trials,* 80 J. Nat'l Cancer Inst. 884 (1988); LaRue, *et al., Acute Stroke Therapy Trials: Problems in Patient Accrual,* 19 Stroke 950 (1988).

As in this case, sponsors of clinical trials regularly turn to medical societies for assistance in identifying physicians willing to participate as medical monitors and clinical investigators. These physicians are often the most important source of patient recruitment in clinical trials. *OTA Report, supra,* at 11; *AMA Special Report, supra,* at 254-55. Recognizing this fact, the National Cancer Institute has launched a drive to increase physician involvement in clinical trials in hopes of doubling patient accrual rates. *AMA Special Report, supra,* at 256.

The Utah Supreme Court's ruling will discourage medical specialty societies and other health care organizations from assisting sponsors in developing clinical trials and in identify-

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[2] As the AMA's Council on Scientific Affairs has stated,

> In the design of [clinical] trials, the establishment of appropriate sample size is necessary to ensure acceptable levels of risk for error when a hypothesis is tested. Thus, it is critical that the predetermined sample size be attained by entering eligible patients in cancer clinical trials in sufficient numbers and in a timely fashion. Presently, clinical research in cancer is being threatened by inadequacies in the accrual of patients for clinical trials.

AMA Special Report, supra, at 254.

ing physicians and dentists willing to participate in such studies, either as medical monitors or as clinical investigators. It also will deter physicians and dentists from agreeing to participate in clinical studies, particularly as clinical monitors. The decision will have a similar impact on academic institutions, non-profit health organizations, non-physician researchers, and any other individual or organization that participates in clinical research activities.

This chilling effect will likely be pronounced because medical and dental societies and individual health care providers participate in clinical trials for reasons other than commercial benefit. Although they may receive some nominal reimbursement for their time and efforts, their primary purpose in participating in clinical trials is to contribute to the advancement of medical science and the improvement of the quality of health care.[3] If the decision below were widely followed by other courts, medical and dental associations and clinical monitors essentially could be subject to jurisdiction in every state in which some phase or aspect of a clinical trial was conducted. In light of the minimal reimbursement that they typically receive for their involvement in clinical research, the threat of being haled into court in a jurisdiction hundreds or thousands of miles away to defend costly, time consuming litigation will almost certainly deter participation in clinical studies

[3] This lack of commercial motive, in and of itself, makes the exercise of jurisdiction particularly inappropriate in this case. *See Kulko v. Super. Court of Calif.*, 436 U.S. 84, 97 (1978) (exercise of jurisdiction violates due process in part because appellant did not seek "a commercial benefit from solicitation of business from a resident of California that could reasonably render him liable to suit in state court"); *State ex rel. Wichita Falls General Hosp. v. Adolf*, 728 S.W.2d 604, 610 (Mo. App.), *cert. denied*, 484 U.S. 927 (1987) (refusing to exercise jurisdiction over nonresident hospital in part because hospital participated in organ donation program for "moral and humanitarian reasons").

by the ablest and most responsible health care organizations and individual health care providers.[4]

The ultimate result will be to stymie the progress of important medical research by making it extremely difficult to attract the key personnel needed to conduct a clinical study. The decision also will directly countermand efforts by the federal government and others to increase patient accrual in national clinical trials in that it will discourage participation by the people best situated to enroll clinically appropriate patients.

Even if the decision below does not completely deter medical societies and physicians from participating in clinical trials, it will at least discourage them from participating in large, multicentered clinical trials involving patients in many states. These large-scale national trials are crucial to the progress of medical research.[5]

Petitioners' limited contacts with Utah must be viewed in light of these adverse consequences for national health

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[4] *See* Kahan, *supra*, at 45 ("if clinical trials of treatments become the target of further litigation, there could be an unwillingness by physicians to participate in such investigations, to the detriment of medicine and society in general") (citing Norman, *Clinical Trial Stirs Legal Battles*, 227 Science 1316 (1985)).

[5] Given the sweeping nature of the Utah Supreme Court's exercise of jurisdiction, its decision may also discourage medical societies from issuing national practice parameters for fear of being subject to jurisdiction in malpractice actions filed in distant forums. Practice parameters are strategies for patient management developed to assist physicians in clinical decision-making. Such parameters play an important role in maintaining and standardizing the quality of patient care and in controlling the overall cost of medical services. Kelly and Swartwout, *Development of Practice Parameters by Physician Organizations*, 16 Quality Rev. Bull. 54 (1990). Many of the *amici* medical specialty organizations issue practice parameters and are concerned about the precedential effect that the Utah Supreme Court's decision will have in malpractice actions in which the use of practice parameters is a liability issue.

care policy. It is particularly unreasonable to exercise jurisdiction where to do so is likely to have such a detrimental effect on clinical research efforts and where petitioners have received no commercial benefit from their attenuated forum contacts. The Utah Supreme Court failed to consider this important aspect of the due process analysis.[6]

II. THE UTAH SUPREME COURT'S FAILURE TO CONSIDER THE EFFECT OF ITS DECISION ON THE AVAILABILITY OF HEALTH CARE SERVICES CONFLICTS WITH THE DECISIONS OF THE MAJORITY OF LOWER COURTS THAT HAVE INTERPRETED THE DUE PROCESS CLAUSE IN MALPRACTICE ACTIONS AGAINST NONRESIDENT HEALTH CARE PROVIDERS.

The practical implications of the Utah Supreme Court's decision for national health care policy extend well beyond its likely effect on the progress of multistate clinical research. If allowed to stand, the decision below is also likely to limit the availability of interstate health care services. By ignoring this additional effect, the ruling below conflicts with the decisions of the majority of lower courts that have been asked to exercise personal jurisdiction over nonresident health care providers in malpractice cases.

Dr. Goldwyn did not diagnose or treat respondent in Utah or anywhere else. The exercise of jurisdiction over Dr. Goldwyn was based solely on his out-of-state activities as medical monitor. He had no other contacts with Utah. Nevertheless, the Utah Supreme Court exercised jurisdic-

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[6] *Amici* do not mean to suggest that respondent is not entitled to any remedy for her injuries. The argument here is not that petitioners are immune from suit, only that it was unreasonable for the Utah Supreme Court to exercise personal jurisdiction over them in light of their limited contacts with Utah and the national interest in maintaining the progress of clinical trials.

tion over him because he engaged in "purposeful acts with known, significant consequences in Utah." Petition at 8a. But this reasoning would apply with even greater force if respondent had traveled to Massachusetts, and Dr. Goldwyn had actually treated her there. In short, the Utah Supreme Court's decision is so overreaching that it arguably encompasses any case in which a nonresident physician treats a Utah patient in a foreign state, and the patient suffers an adverse reaction after returning to Utah.

In view of its sweeping rationale, the Utah Supreme Court's decision will not only have a specific deterrent effect on participation in clinical trials, it will also have a more generalized chilling effect on the willingness of nonresident physicians and health care providers to treat Utah patients outside of Utah. If this Court allows the Utah Supreme Court's ruling to stand, other state and federal courts will be more likely to follow it. The ultimate effect will be to balkanize our interstate system of health care. Citizens of one state will find that state boundaries constitute an impenetrable barrier to securing the best, and sometimes the *only*, available health care services—*e.g.*, heart and liver transplants, cancer therapy, kidney dialysis, and other sophisticated treatments.[7] In metropolitan areas that cut across state lines, the result would be to encourage the duplication of highly sophisticated facilities. Such results conflict with the "shared interest of

[7] By discouraging participation in multistate clinical trials, the Utah Supreme Court's decision also will have the more immediate effect of limiting the availability of state-of-the art therapies offered by clinical trials. Hunter, *supra*, at 559. In many cases, a patient's only hope for recovery is by undergoing an experimental treatment. *Report of the Presidential Commission on Human Immunodeficiency Virus Epidemic* 54 (1988) (advocating greater access to drug trials to provide the hope and possibility of treatment for thousands of HIV patients).

the several States," *World-Wide Volkswagen*, 444 U.S. at 292, in ensuring that specialized health care services are available to all citizens, regardless of which state they live in, at the lowest possible cost.

By failing to consider or give credence to the effect of its decision on access to interstate health care services, the Utah Supreme Court not only disregarded the decisions of this Court, *Asahi*, 480 U.S. at 113; *World-Wide Volkswagen*, 444 U.S. at 292, it also has positioned itself in direct conflict with the preponderance of courts that have addressed the personal jurisdiction issue in malpractice actions against nonresident physicians and other health care providers.

There is now a long line of cases, starting with the Ninth Circuit's decision in *Wright v. Yackley*, 459 F.2d 287 (9th Cir. 1972), in which courts interpreting the Due Process Clause have *refused* to exercise jurisdiction over nonresident physicians or health care providers, either in whole or in part, because to do so could have the effect of restricting the availability of interstate health care services. In almost all of these cases, the defendant health care provider had greater contact with the forum state than Dr. Goldwyn had with Utah in this matter.

In *Wright*, the Ninth Circuit held that it would violate the Due Process Clause to exercise jurisdiction in Idaho over a South Dakota physician. The physician had initially treated a patient in South Dakota. After the patient moved to Idaho, the physician mailed copies of the patient's prescription to an Idaho pharmacist. The court held that in cases of personal services, the focus should be on the places where the services are rendered. It stated that:

> In our opinion, a state's dominant interest on behalf of its citizens in such a case as this is not that they should be free from injury by out-of-state doctors, but

> rather that they should be able to secure adequate medical services to meet their needs wherever they may go. 459 F.2d at 291.

The court concluded that it would be unreasonable to exercise jurisdiction over the nonresident physician.

Likewise, in *Gelineau v. New York Univ. Hosp.*, 375 F. Supp. 661, 667-68 (D.N.J. 1974), the court, relying on the reasoning in *Wright*, found that due process would not permit the exercise of jurisdiction in New Jersey over a New York hospital and its blood suppliers in a case in which a New Jersey patient was allegedly given an infected blood transfusion in the New York hospital. The court stated that the exercise of jurisdiction

> . . . would have a chilling effect on the availability of professional services to non-residents. Professionals in the medical field, for example, concerned with one of the most rapidly advancing sciences of modern times, would be hesitant to treat a non-resident if they knew that thereafter, upon the receipt of a registered letter, they could be compelled to travel to a foreign state, and there to account, under the laws of that state, for the services which were sought from them and rendered by them at home. *Id.*

In *Simmons v. State*, 206 Mont. 264, 670 P.2d 1372 (1983), the Montana Supreme Court followed *Wright* and *Gelineau* in finding that it was unreasonable to exercise jurisdiction over the Health Division of the Oregon Department of Human Resources for alleged negligent testing of metabolic disorders in a newborn child. The Oregon agency provided this testing service to several nearby states that lacked the capability to perform it themselves.

The *Simmons* court stated that "[t]he reasonableness of asserting jurisdiction over Oregon must also be assessed in light of the shared interest of both Montana and Oregon in advancing the state of quality medical testing technology." 670 P.2d at 1383. It concluded that:

> If we found that jurisdiction was reasonable under the given facts, we would be creating precedent for jurisdiction over Oregon by other states that contracted with it for regional blood testing services. In that event, we think it highly likely that Oregon might refrain from providing the service rather than risk defending its interests in the several foreign states. Thus, we find that proper respect for the mutual interests of interstate access to medical services and quality rendering of those same services requires that plaintiff pursue his malpractice claim in the Oregon courts. *Id.* at 1384.

In *State ex rel. Wichita Falls General Hosp. v. Adolf*, 728 S.W.2d 604, 610 (Mo. App.), *cert. denied*, 484 U.S. 927 (1987), the Missouri Court of Appeals cited similar reasons for refusing to exercise jurisdiction over a Texas hospital that provided the wrong type of organ donor heart to a patient in Missouri:

> If the threat of having to defend a potential malpractice action, meritorious or otherwise, in a far distant jurisdiction serves to cause even one hospital to refuse to provide an organ necessary to keep a Missouri resident alive the results far outweigh the inconvenience of requiring Missouri residents to sue in the hospital's home forum. *Id.*

The majority of published decisions in malpractice cases against nonresident physicians and other health care providers have agreed with the balance of interests analysis used in *Wright*, *Gelineau*, *Simmons*, and *Wichita Falls* and thereby dismissed such actions for lack of personal jurisdiction.[8] This is precisely the approach that is re-

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[8] *See, e.g., Rann v. McInnis*, 789 F.2d 374, 376 (6th Cir. 1986); *Wolf v. Richmond County Hosp. Auth.*, 745 F.2d 904, 911 (4th Cir. 1984), *cert. denied*, 474 U.S. 826 (1985); *Lemke v. St. Margaret Hosp.*, 552 F. Supp. 833, 837 (N.D. Ill. 1982) (subsequent history

(Footnote continued on following page)

quired by this Court's decisions in *Asahi* and *World-Wide Volkswagen.*

The Utah Supreme Court's decision is not just an isolated aberration. At least two other courts have exercised jurisdiction over nonresident health care providers in malpractice actions, in spite of the possible adverse effects on the availability of interstate health care services. For instance, in *McGee v. Riehkof*, 442 F. Supp. 1276 (D. Mont. 1978), the Montana district court exercised jurisdiction over an out-of-state ophthalmologist who had treated a Montana patient in Utah and then gave an allegedly negligent telephone diagnosis to the patient after the patient had returned to Montana. The court recognized the need to preserve access to interstate medical services, but ruled that this need was outweighed by Montana's interest in deterring malpractice by nonresident physicians. This conclusion not only conflicts with *Wright* and its progeny, it is in direct opposition to the Montana Supreme Court's subsequent decision in *Simmons*. Likewise, just last year, the United States Court of Appeals for the Tenth Circuit held that the forum state's interest in deterring medical malpractice against its residents outweighs the "incremental deterrent effect on doctors who provide health care to citizens of foreign states." *Kennedy v. Freeman*, 919 F.2d 126 (10th Cir. 1990) (exercising jurisdiction over Texas physician who allegedly made a misdiagnosis of a cancerous skin lesion that was sent to him by an Oklahoma physician on behalf of an Oklahoma patient).

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[8] *continued*
omitted); *Hume v. Durwood Medical Clinic, Inc.*, 318 S.E.2d 119, 123 (S.C. App. 1984), *cert. denied*, 474 U.S. 848 (1985); *Woodward v. Keenan*, 79 Mich. App. 543, 261 N.W.2d 80, 83 (1978) (subsequent history omitted).

Thus, the Utah Supreme Court's decision adds to a significant conflict among the lower courts regarding the importance of the availability of interstate health care services where courts are asked to exercise personal jurisdiction over nonresident health care providers. As a result, whether a physician, dentist or other health care provider is subject to long-arm jurisdiction for allegedly mistreating an out-of-state patient now depends to a large extent on the fortuity of the patient's state of domicile. In some states, *e.g.*, Montana, the jurisdictional decision may turn on whether the provider is sued in federal or state court.

This is hardly the type of predictability that the Due Process Clause is supposed to provide nonresident defendants. *World-Wide Volkswagen*, 444 U.S. at 297. Health care providers are entitled to know the type of conduct and connection with a forum state that make it reasonable for them to "anticipate being haled into court there." *Id.*

This Court should grant the petition and review this case to resolve the conflict in the courts below by providing a uniform interpretation of the jurisdictional requirements of the Due Process Clause in malpractice actions involving nonresident health care providers and organizations.

CONCLUSION

For the foregoing reasons, *amici* respectfully request that the petition for a writ of certiorari be granted.

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